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EXAMINER
SHAPIRO, JEFFERY A

ART UNIT	PAPER NUMBER
3653	

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,599	TOD, JR., G. ROBERT	
	Examiner	Art Unit	
	Jeffrey A. Shapiro	3653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,22,23,31-35,39-42,44-52 and 67-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,22,23,31-35,39-42,44-52 and 67-70* is/are rejected.

7)☒ Claim(s) *44 and 70* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claims 44 and 70 are objected to because of the following informalities: over-the-counter is hyphenated in some recitations and unhyphyenated in others. Claims 44 and 70 are given as examples. If the hyphenated recitation is desired, all recitations throughout the claims and the specification should be made consistent. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-15, 22, 23, 31-35, 38-42, 44-52 and 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liff et al (US 6,068,156). Liff et al discloses the following.

As described in Claims 1, 22, 31, 35 and 44;

1. one or more dispensers (20) configured to controllably release a product in response to a control signal;

2. an admission subsystem (see element (311) and figure 13P) configured to maintain patient information;

3. a prescription subsystem coupled to said one or more dispensers and configured to:

a. receive entry of prescription information;

b. to relate patient information from said admission subsystem to the prescription information to initiate a determination of whether the product is appropriate for the patient;

c. to send a control signal to said one or more dispenser units to release the product;

(See col. 23, lines 12-37, which includes an adjudication step at line 16) As described in Claims 2, 31, 35, 44 and 46;

4. said determination of whether the medication is appropriate for the patient comprises a pharmacy adjudication (see col. 23, line 16);

As described in Claim 3;

5. said determination of whether the medication is appropriate for the patient comprises a drug utilization review (DUR) (see figure 12, and element (284);

As described in Claims 4, 32 , 33, 36, 37 and 3;

6. said prescription subsystem is further configured to manage and control a virtual inventory by tracking ownership and utilization of a plurality of individually owned and co-mingled inventories in said one or

more dispensers (note that various inventories are kept track of, including the inventory of several cabinets, and that virtual and actual inventories are functionally equivalent to each other—also note that pharmaceutical companies are also connected to the system, and they necessarily have inventory systems of their own, which necessarily interface with the system of Liff et al);

As described in Claims 5, 34 and 38;

7. access to a medication inventory is further controlled according to ownership of the medication as tracked in said virtual inventory (note that it is necessary for the medication to be matched with the appropriate patient and for medicines in a dispensing cabinet at hospital X to be identified as located at hospital X's cabinet);

As described in Claims 6 and 39;

8. said prescription subsystem is configured to manage and control a physical inventory by sending a reorder message to reorder a product when an inventory level is at a predefined level (note refill function (310), noting that pharmaceuticals are routinely given to patients with the number of refills located on the label, said refill occurring for a particular number of units of that pharmaceutical);

As described in Claims 7 and 40;

9. the predefined level comprises a par inventory level (note that it is well-known in the art to use predefined levels to trigger refills—see also figure 7C, element (182));

As described in Claims 8 and 41;

10. the predefined level comprises a dynamic par level that is based upon medical office product usage data (note that it is well-known and necessary for an inventory system to track inventory and inventory levels on a dynamic basis in order to perform adequate forecasting of needs);

As described in Claim 9;

11. said admission subsystem generates a patient specific drug benefit profile used in prescribing the medication (see elements (336, 337 and figure 13E);

As described in Claims 10, 23 and 51;

12. a sample management subsystem configured to track the distribution of a sample medication to a patient, to associate information gathered from the distribution of the sample medication with said patient information, to initiate a determination of whether the information is appropriate for the patient, and to send a control signal to said one or more dispenser units to release a sample medication (see figures 7B, 7C and 8, noting in figure 8, phase I is directed toward a toxicity levels, phase II is directed towards safety, phase II, toward efficacy and phase IV, to distribution—note also that figure 8 describes administration of drugs

during a clinical trial, which can be construed as a functional equivalent of a "sample" distribution);

As described in Claim 11;

13. a patient care subsystem configured to relate said patient information to data collected from the dispensing of an office administered medication and to send a control signal to said one or more dispenser units to release a product (see figure 2, elements (108 and 120);

As described in Claim 12;

14. an over-the-counter subsystem configured to relate said patient information to data collected from the dispensing of an over the counter product, further configured to send a control signal to said one or more dispenser units to release the over-the-counter-product (note that dispensing a prescription or over-the-counter drug is construed to be handled in the same substantially the same fashion, using the same equipment and structure, therefore it is concluded that the system of Liff et al is capable of handling over-the-counter drugs);

As described in Claim 13;

15. the medication is dispensed at a point of care (note that the medication can be dispensed at a hospital or doctor's office, for example, and that any particular place, including a patient's home could conceivably be the location of a cabinet that is secure);

As described in Claims 14 and 44;

16. a central server (422) (see also element (573, figure 17, which indicates an internet which implies the presence of a server) connected via a network to said prescription subsystem and configured to receive and process said determination of whether the medication is appropriate for the patient;

As described in Claims 15, 42 and 45;

17. said central server is coupled to an enterprise resource planning (ERP) system having an accounting module configured to track finances and collection of money, an inventory module configured to manage physical and virtual product inventories, a purchasing module configured to automatically process purchase requests, and a fulfillment module configured to manage product order requests (note that at the very least, these limitations are obvious to one ordinarily skilled in the art to provide, otherwise, the system of Liff et al would not work);

As described in Claim 47;

18. a user support module including user training and learning modules (note that a user support module, such as described in col. 11, lines 65-67 and col. 12, lines 1-14 would be expected to include learning and training modules);

As described in Claim 48;

19. said central system comprises a website connected to the central server, wherein said website is configured to provide controlled user

access to system information (see figure 17, for example, which indicates use of the internet, and that the system of Liff et al would obviously require some form for communicating over the internet and that it would be expedient for one ordinarily skilled in the art to use a website in order to work in conjunction with the internet, as described in figure 18, for example);

As described in Claim 49;

20. said system information is able to be outputted in the form of a report (see figure 13Q, noting element(442));

As described in Claim 50;

21. a front office server coupled to said one or more dispensers and comprising an admission subsystem and said prescription subsystem, said front office server configured to serve patient information (note prior discussion on location of cabinets in a wide variety of places);

As described in Claim 52;

22. said central system performs system maintenance and monitoring (see col. 11, lines 65-67 and col. 12, lines 1-14);

Applicants' amendment filed 6/9/03 includes the following significant new limitations and changes.

As described in Claims 1, 11, 12, 22, 34, 35 and 44;

1. A sample management subsystem coupled to said one or more dispensers and configured to track the distribution of a sample medication to a patient, to initiate a determination of whether the medication is appropriate for the patient, and to send a control signal to said one or more dispenser units to distribute a sample medication (see above discussions of clinical trials, for example, in figure 8);

2. the word "release" has been replaced by "distribute";

As described in Claims 2, 3, 5, 11 and 14;

3. the word "medication" has been replaced by "product";

As described in Claim 23;

4. the words "or the sample medication" has been added;

As described in Claim 31;

5. a marketing module in communication with said patient information database and said prescription module, the marketing module configured to gather product usage data, to transmit said product usage data, and to receive, in response to the transmission of said product usage data, marketing information for an individual dispensing the product and/or a patient (note that the system of Liff et al stores such information as patient records and that it would, at the very least, be expedient for one ordinarily skilled in the art to use and manipulate such data to determine sales and marketing objectives, the information being, for example, what products were bought by what type of patients and under what circumstances);

As described in Claim 32;

6. a central system comprising a central server in communication with said marketing module, which central system is configured to receive the transmission of said product usage data and to determine appropriate marketing information to direct to an individual dispensing the product and/or said patient (the marketing information can also be argued to be educational information, since drug marketing information is essentially the same as educational information, discussed above, as taught by Liff et al);

As described in Claim 34;

7. the word "based" has been replaced by "contingent"

As described in Claim 35;

8. an inventory management module configured to control and manage the physical inventory and the virtual inventory of the product, said control and management of said virtual inventory tracking ownership and dispensing of a plurality of individually owned and co-mingled product inventories in said one or more dispensers; (Applicants argue that virtual inventory is different because of the "co-mingling" of inventories, for example, between different doctors in the same practice who use the same dispenser. However, virtual inventories are the same as regular inventories in that they are discrete from each other. In addition, various patients have accounts particular to themselves as do doctors/healthcare

providers and pharmacists. See col. 13, lines 7-12, describing that the system monitors patient records and billings and that patient records are accessed on an integrated basis. See also col. 13, lines 28-38, describing that pharmaceuticals are tracked using bar code information and that accounts receivable, accounting and inventory management modules are integrated. Therefore, at the very least, it would have been obvious to one of ordinary skill in the art to use the information already available-that is the patient records with the doctor and drug dispensed information to account for drugs to a specific doctor in a multi-doctor practice.)

As described in Claim 44;

9. an over-the-counter subsystem coupled to said one or more dispensers and to said central system, and configured to relate said patient information to data collected from the dispensing of an over-the-counter product, further configured to send a control signal to said one or more dispenser units to distribute the over-the-counter product (again, this is considered to be obvious to one of ordinary skill in the art to use the system of Liff et al in an over-the-counter environment, since the basic modules, structure and function of dispensing drugs are readily adaptable to this or other environments, such as home, supermarket, or other remote location);

New Claims 67-70 have been added, as follows.

As described in Claim 67;

10. a marketing subsystem configured to track and report the use of the product or sample medication and to associate said patient information with said use of the sample medication thereby determining appropriate marketing information to direct to said patient (again, note the educational information Liff et al dispenses along with the drugs);

As described in Claim 68;

11. a marketing subsystem configured to track and report the use of the product or the sample medication (again, see figure 8 and prior discussion);

As described in Claim 69;

12. said one or more dispensers configured to controllably distribute a product in response to a control signal by dispensing, releasing or granting access to the product (see prior discussion);

As described in Claim 70;

13. said marketing subsystem is further configured to track and report use of a sample medication and an over-the-counter product and to associate said patient information with said use of the sample medication or the over-the-counter product thereby determining appropriate marketing

information to direct to an individual dispensing the sample medication or the over-the-counter product and/or said patient (see prior discussion);

Response to Arguments

4. Applicant's arguments filed 6/9/03 have been fully considered but they are not persuasive. Applicants' limitations presented in the independent claims, reasonably broadly construed, appear to read on the prior art used in the rejections as well as the cited prior art. It is suggested that Applicants' arguments regarding the aspects described in the specification are not recited in the claims. Applicants' Representative is encouraged to contact the Examiner regarding directions for further amendments.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rosenblum, Uecker et al, Cunningham, Stevens, and Silver are cited as further examples of the prior art regarding dispensing and marketing systems for pharmaceuticals.

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey A. Shapiro whose telephone number is (703)308-3423. The examiner can normally be reached on Monday-Friday, 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald P. Walsh can be reached on (703)306-4173. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1113.

Jeffrey A. Shapiro
Examiner
Art Unit 3653

August 24, 2003

DONALD P. WALSH
SUPERVISORY PATENT EXAMINER
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